

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

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# MEMORANDUM

**SUBJECT:** EFED Response to the MCPA Waiver Request for a Fish Bioconcentration Factor

(BCF) Study in Response to the Registration Review Data Call-in (GDCI-

030501-1452)

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This memorandum transmits the Environmental Fate and Effects Division's (EFED) response to the MCPA Task Force Three's second waiver request regarding the data call-in (GDCI-030501-1452) for the registration review of MCPA. The July 31, 2015 MCPA data call-in included a data requirement for a fish bioconcentration factor (BCF) study (OSCPP Guideline 850.1730) conducted with MCPA 2-ethylhexyl ester (MCPA 2-EHE) technical grade active ingredient (TGAI).

On April 25, 2017, the MCPA Task Force Three submitted their first waiver request for a Fish Bioconcentration Factor (BCF) study (OPPPTS 850.1730) which included very limited information from a pilot study (MRID 50267301). Based on the review of the submitted information, completed on September 5, 2017 (DP440802), EFED deemed the data were not sufficient to evaluate the BCF waiver request. EFED requested that a more detailed study report of the pilot study be submitted for Agency review.

In their recent submission, the MCPA Task Force Three submitted the requested additional information; i.e. fish body weight and lipid measurements, properties of the water (i.e. pH,

temperature etc.) and raw data for analysis [MRIDs: 50418400 (cover letter), 50418401 (study), and 50418402 (raw data)] to support the MCPA 2-EHE BCF waiver request.

## **Registrant Rationale:**

The registrant determined that MCPA 2-EHE has low functional water solubility of approximately 0.005 mg/L. In abiotic aqueous system MCPA 2-EHE readily converts into MCPA acid due to hydrolysis and in biotic aquatic system initially adsorbs onto the soil particles, and then undergoes microbial degradation to MCPA acid. The formation of MCPA acid appears more rapid in the biotic system containing fish. MCPA ester is hydrophobic and readily adsorbs into biological material as well as laboratory glassware. According to the registrant, the chemical tendency for adsorption into available non-aqueous surfaces combined with low water solubility, and rapid conversion to MCPA acid made it challenging to conduct the testing according to OPPTS 850.1730 or OECD TG 305 standard protocol. Therefore, the registrant conducted a series of experiments to find appropriate conditions to conduct a bioconcentration study and then performed a pilot experiment; an uptake depuration trial. The results of the pilot study indicate that MCPA 2-EHE BCF is approximately 61 at day 2 and undergoes rapid depuration (DT<sub>50</sub>) of approximately 24 hrs from day 2 to day 3 (MRID 50418401, p. 16). These data indicate that MCPA 2-EHE has low potential to bioaccumulate in fish.

### **EFED Response**:

EFED recommends that the waiver request be granted based on the review of the original pilot study submission (MRID 50267301) and the additional data recently provided by the registrant (MRIDs 50418401 and 50418402). No additional data is required for MCPA 2-EHE TGAI fish BCF study (OSCPP Guideline 850.1730) at this time.

#### **References:**

MRID 50267301. Schofield C. M., 2017. Request for a Waiver for a Fish Bioconcentration Factor (BCF) Study (OPPTS 850.1730) in Response to Generic Data Call-In Notice ID # GDCI-030501-1452 dated 31 July 2015 for MCPA (and Salts and Esters) (Chemical #030501). Submitted by MCPA Task Force Three, Raleigh North Carolina. Document identification: MCPATF-850.1730\_04252017. April 25, 2017, pp 33.

MRID 50418401. Tom Teak, 2018. <sup>14</sup>C-MCPA-EHH: Non-GLP Solubility and Stability Investigations in a Test System to be Used for a Pilot Bioconcentration Study with Bluegill, *Lepomis macrochirus*. Amended Final Report. Study sponsored and submitted by MCPA Task Force Three Raleigh, North Carolina, and performed by Analytical Bio-Chemistry Laboratories, Inc. Study No. 84350. Study completion date: October, 2017. pp 43.

MRID 50418402. <sup>14</sup>C-MCPA-EUE: Non-GLP Solubility and Stability Investigations in a Test System to be Used for a Pilot Bioconcentration Study wilii Bhiegill, *Lepomis macrochinis*. Study sponsored and submitted by MCPA Task Force Three, Raleigh, North Carolina, and performed

by Analytical Bio-Chemistry Laboratories, Inc. Study No. 84350. Report completion date: October 10, 2017, pp 837.